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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,353

10/10/2002

Guenther Eberz

Mo6996/LeA

8113

7590

03/25/2005

Bayer Corporation
Patent Department
100 Bayer Road
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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,353

Applicant(s)

EBERZ ET AL.

Examiner

Kathleen M. Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-67 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,7-67 and 70-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment, Claims 1-5, 7-67, and 70-72 are pending in the instant application.

Restriction

2. Restriction is required under 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicant is required, in reply to this action, to elect a single invention (Group, *not* SuperGroup) to which the claims must be restricted.

SuperGroup A (Groups 1-69), claim(s) 1-12, 14-30, and 65, drawn to nucleic acids coding for an enzyme activity, one of 69, involved in spinosyn biosynthesis.

Group 70, claim(s) 13, drawn to a regulatory region from *S. spinosa*.

SuperGroup B (Groups 71-140), claim(s) 31-62, drawn to polypeptides involved in spinosyn biosynthesis.

SuperGroup C (Groups 141-210), claim(s) 63, drawn to antibodies specific for polypeptides involved in spinosyn biosynthesis.

SuperGroup D (Groups 211-280), claim(s) 64, drawn to methods of making nucleic acids coding for an enzyme activity, one of 69, involved in spinosyn biosynthesis.

SuperGroup E (Groups 281-350), claim(s) 66-67, drawn to methods of making spinosyn-like compounds using nucleic acids coding for an enzyme activity, one of 69, involved in spinosyn biosynthesis.

Group 351, claim(s) 70, drawn to methods of glycosylating a spinosyn using SEQ ID NOs:23, 25, 29, 31, 33, 35, and 37 (using all 7 nucleic acid sequences).

SuperGroup F (Groups 352-357), claim(s) 71-72, drawn to methods of glycosylating a spinosyn using particular nucleic acids involved in spinosyn biosynthesis.

Art Unit: 1652

In SuperGroup A, further restriction to one of Groups 1-69, encompassing some of claim(s) 1-12, 14-30, and 65, is required. Said Groups 1-69 are drawn to the regions identified on pages 12-18 of the specification as ORFs 1-17, defined portions (50 in all) of ORFs 18-22, ORF 23, and ORF 24.

In SuperGroup B, further restriction to one of Groups 71-140, encompassing some of claim(s) 31-62, is required. Said Groups 71-140 are drawn to the enzymes defined as being encoded by the regions on pages 12-18 as noted above for SuperGroup A.

In SuperGroup C, further restriction to one of Groups 141-210 is required. Said Groups 141-210 are drawn to the antibodies specific for the enzymes defined as being encoded by the regions on pages 12-18 as noted above for SuperGroup A.

In SuperGroup D, further restriction to one of Groups 211-280 is required. Said Groups 211-280 are drawn to the methods of making particular nucleic acids encoded by the regions on pages 12-18 as noted above for SuperGroup A.

In SuperGroup E, further restriction to one of Groups 281-350, encompassing some of claim(s) 66-67, is required. Said Groups 281-350 are drawn to the methods of using nucleic acids that are regions identified on pages 12-18 of the specification as ORFs 1-17, defined portions (50 in all) of ORFs 18-22, ORF 23, and ORF 24.

In SuperGroup F, further restriction to one of Groups 352-357, encompassing some of claim(s) 71-72, is required. Said Groups 352-357 are drawn to using SEQ ID NOs: 7, 9, 11, 13, 17 or 19, respectively.

3. The inventions listed as Groups 1-357 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed genus of Group 1 lacks a special technical feature because the claim, as a whole, does not contribute over the prior art.

“An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions

Art Unit: 1652

claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any)." (see M.P.E.P. § 1850)

Spinosyn biosynthesis genes are taught by Baltz *et al.* (see IDS for USPN 6,143,526 filed on March 9, 1998). Even considering Applicant's foreign priority claims, USPN 6,143,526 is considered prior art, as of its filing date, by more than a year. Thus, the genus of any nucleic acid encoding a region coding for an enzyme activity involved in spinosyn biosynthesis does not contribute over the prior art as a whole.

Since the technical feature of Group 1, namely the sequence as described in pages 12-18, is not a special technical feature, none can be shared with the other Groups as listed above. The products of Groups 1-69 are grouped separately because they have different technical features, i.e., different nucleotide sequences. The same is true of Groups 71-140 (different protein sequences) and 141-210 (antibodies recognizing different protein sequences). Groups 1-69, while being the same generic structure of a nucleotide sequence as that of the product of Group 70, are different from Group 70 by virtue of the different nucleotide sequences disclosed. Groups 1-70 are different products from the products of Groups 71-140 and of Groups 141-210; said Groups are drawn to nucleotide sequences, protein sequences, and antibodies, respectively; and their structures are different since polypeptides (contiguous sequences of amino acids) are different from nucleic acids (contiguous sequences of nucleotides) are different from antibodies (contiguous sequences of amino acids different from that of the polypeptides in their sequence).

Art Unit: 1652

While their structures correspond to each other, without a special technical feature of Group 1, this is insufficient to be grouped together (see M.P.E.P. § 1850):

“The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product; or
- (B) In addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process; or
- (C) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process...

A single general inventive concept must link the claims in the various categories and in this connection the wording above should be carefully noted.” (emphasis added, see M.P.E.P. § 1850)

Moreover, the methods of Groups 211-357 are of different categories (methods as opposed to products) with respect to Groups 1-210. Since unity is lacking in Group 1, the different categories need not be grouped together as noted above. Thus, the instant claims have been appropriately restricted according to lack of unity practice as the claims lack a common special technical feature, are of different categories of invention, and/or the products are not specifically adapted for use in the claimed methods.

Groups within SuperGroups D, E, and F are different by virtue of using different nucleotide and/or protein sequences as described above.

Notice of Possible Rejoinder

4. The Examiner notes that the instant application is a national stage entry of PCT/US00/08013 filed under 35 U.S.C. § 371. For purposes of restriction, lack of unity practice has been applied to the pending claims under 35 U.S.C. § 121 and 372. Lack of unity will be reassessed at each stage of prosecution hereafter.

Election

5. Applicant is advised that the reply to this requirement to be complete **must include an election of the invention (a Group, one of 357)** to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

March 15, 2005